510(k) Summary

JUL 18 2012

As required by 21 CFR 807.87(h), a 510(k) Summary for this Premarket Notification submission is provided below.

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

PHILIPS

ST80i Stress Test System

Submitter's Name and Address

Submitter's Name:	Philips Healthcare
Division:	Diagnostic ECG
Address:	1525 Rancho Conejo Boulevard Suite 100
City, State, and Zip:	Thousand Oaks, CA 91320
Contact Name:	Gretel Lumley/Quality and Regulatory Engineer
Telephone / Fax:	(805) 214-5101 / (805) 214-5129

Manufacturers' Information: Establishment Registration Number

Establishment name:	Philips Medical Systems
Address:	3000 Minuteman Road Andover, MA 01810
Establishment Registration No.	1218950

Device Details

	New Product	Predicate
Proprietary or Trade Name:	ST80i Stress Test System	CASE V6.6 and CS V6.6 Cardiac Testing System
Common Name:	ECG Analysis Computer	ECG Analysis Computer
Device Class:	II	II
Device ProCodes:	DQK	DQK
Device CFR:	870.1425	870.1425
Classification Panel:	74 Cardiovascular	74 Cardiovascular
Classification Name:	Programmable diagnostic computer	Programmable diagnostic computer

Intended Use

The Philips ST80i Stress Test System is a PC-based diagnostic tool intended to acquire, process, and store ECG data of patients undergoing stress exercise testing. The software records ECG, heart rate, and ST data, creates summary tables, trends, and produces a final report regarding a variety of cardiac data indices. The cardiac data provided by the Stress system is intended to be reviewed, confirmed, and used by trained medical personnel to assist in the evaluation of the patient's cardiovascular condition and the patient's physiological condition during stress exercise testing. The arrhythmia detection portion of the ST80i Stress Exercise System is provided to the user for the convenience of automatic detection of arrhythmias but does not provide alarms.

Indications for Use:

The Philips ST80i Stress Test System is indicated for use in exercise ECG testing where the clinician decides to evaluate the electrocardiogram of patients at 10 years or older, as part of decisions regarding possible diagnosis, potential treatment, effectiveness of treatment or to rule out causes for symptoms of cardiovascular disease. The Philips ST80i Stress Test System is not intended to be used as a physiological monitor.

Device Description

The ST80i Stress Test System is a PC-based diagnostic tool intended to acquire, process, and store ECG data (resting and physiologic) of patients undergoing stress exercise testing and acquire data from ancillary devices (such as SpO_2 and Ambulatory Blood Pressure). The software records ECG, heart rate, and ST data, creates summary tables, trends, and produces a final report regarding a variety of cardiac data indices. The arrhythmia detection portion of ST80i Stress Testing System is provided to the user for the convenience of automatic detection of arrhythmias but does not provide alarms. The cardiac data provided by the stress system is intended to be reviewed, confirmed and used for diagnostic purposes by trained medical personnel to assist in the diagnosis of coronary artery disease (CAD) and the patient's physiological condition during stress exercise testing. The ST80i Stress Test System will be offered in two versions which are a complete turnkey system which includes an ECG data acquisition module, trolley with a PC loaded with the application software and optional thermal printer or a minimal system with the application software and data acquisition module only.

Product Comparison:

Specification / Feature	ST80i Stress Test System	CASE V6.6 and CS V6.6 Cardiac Testing Systems	Comparison
Indications for Use	**Intended Use:** The Philips ST80i Stress Exercise System is a PC-based diagnostic tool intended to acquire, process, and store ECG data of patients undergoing stress exercise testing. The software records ECG, heart rate, and ST data, creates summary tables, trends, and produces a final report regarding a variety of cardiac data indices. The cardiac data provided by the Stress system is intended to be reviewed, confirmed, and used for diagnostic purposes by trained medical personnel to assist in the diagnosis of CAD and the patient's physiological condition during stress exercise testing. The arrhythmia detection portion of the ST80i Stress Exercise System is provided to the user for the convenience of automatic detection of arrhythmias but does not provide alarms	**Intended Use:** CASE Cardiac Testing System and the CS Cardiac Testing System are intended to be used by trained operators under direct supervision of a licensed health care practitioner on adult and pediatric patients. The CASE Cardiac Testing System and the CS Cardiac Testing System are designed to acquire, process, record, archive, analyze and output (12 and 15 lead) ECG data during a period of physiologic stress or during a resting ECG test, acquire data from ancillary devices (such as spirometryand Ambulatory Blood Pressure), provide median morphology recordings and record ECG in real-time with and without arrhythmia detection. The arrhythmia detection portion of CASE Cardiac Testing System and the CS Cardiac Testing System are provided to the user for the convenience of automatic detection of arrhythmias but does not provide alarms. CASE Cardiac Testing System and the CS Cardiac Testing System provide the control of external devices typically a treadmill or Ergometer) and communicate with centralized electronic/digital storage system via network. CASE Cardiac Testing System and the CS Cardiac Testing System provide a user selectable option for printouts of prognostic scores on select reports. Vector loops are also available. CASE Cardiac Testing System and the CS Cardiac Testing System can be configured in a network environment for multiple CASE or CS stations allowing the user to create a central database of patient demographics and collected patient physiological data. CASE Cardiac Testing System and the CS Cardiac Testing System are intended to be used primarily in the hospital but can be used in clinics, physician offices, outreach centers or wherever exercise, stress testing, ECG, spirometryor ambulatory blood pressure testing is performed. CASE Cardiac Testing System and CS Cardiac Testing System offer no diagnostic opinion to the user. Instead it provides interpretive statements of morphology, rhythm and conductions for which the physician renders his/her own medical opinion. CASE Cardiac Testing System and CS Cardiac Testing System are not intended to be used as a transport device or for home use. CASE Cardiac Testing System and CS Cardiac Testing System are not intended for the use as a vital signs physiological monitor or for intracardiac use.	Similar
Target Population	Adult and Pediatric	Adult and Pediatric	Same

Specification / Feature	ST80i Stress Test System	CASE V6.6 and CS V6.6 Cardiac Testing Systems	Comparison
Where Used	Healthcare facilities	Used in a hospital or facilities providing exercise, stress testing, ECG, spirometryor ambulatory blood pressure testing.	Similar
Sampling Rate	1000 samples per second	500 samples per second	Different
Bandwidth	.050 – 150 Hz	.050 – 150 Hz	Same
Input Signal Resolution	5μV/LSB at 1000 Hz	4.88μV/LSB at 500 Hz	Similar, Hz difference is due to sampling rate
Notch Filter	Yes, configurable	Yes, Configurable	Same
Baseline Correction	Cubic Spline Algorithm	Cubic Spline Algorithm	Same
Artifact/Baseline Correction	No	Finite Residual Filter (FRF) Analysis	Different, did not implement FRF due to potential distortion of ST segment
ST Measurements	ST amplitude, ST Slope, index, ST/HR index	ST amplitude, ST Slope, integral, index, ST/HR slope, ST/HR loops, ST/HR index up to 15 leads	Similar
Heart Rate	Automatic Arrhythmia detection, documentation and annotation	Automatic Arrhythmia detection, documentation and annotation	Same
Post J-Point selection	Configurable	Configurable	Same
QRS detection and analysis	Automatic or manual lead selection	Automatic or manual lead selection	Same
ECG Output	Real-time ECG/TTL or analog synchronization output	Real-time ECG//QRS beep/TTL synchronization output	Similar
Full-disclosure ECG	Beat-to-beat ECG storage and event review	Beat-to-beat ECG storage and event review	Same
Reanalysis	Post-test medians measurements from J point selections	Post-test medians measurements from E, J and post-J point selections	Similar
ECG interpretation	Philips ECG Algorithm (resting ECG analysis program for adults and pediatrics)	(Optional) Marquette 12SL resting ECG analysis program for adults and pediatrics	Similar
Technology	Battery powered 10-channel acquisition module with built-in lead-fail detection and lead prep impedance measurement. The applied part is type CF.	Active, "Type BF" floating isolated powered 14-channel acquisition module with built-in lead-fail detection and lead prep impedance measurement	Similar

Specification / Feature	ST80i Stress Test System	CASE V6.6 and CS V6.6 Cardiac Testing Systems	Comparison
Dynamic Range	300 mV	320 mV ± 10 mV signal superimposed on ± 150mV DC offset	Similar
Noise	< 20 uV peak-to-peak noise over 0.02 to 300 Hz (-3 dB) bandwidth	< 15 uV peak-to-peak noise over 0.01 to 150 Hz (-3 dB) bandwidth	Similar
Frequency Response	-3dB display and writer	-3dB display and writer	Same
High Pass Filter	0.02, 0.05, 0.15 (selectable)	0.01(or 0.05 Hz, special use) with DC offset control	Similar
Low Pass Filter	40,100,150,300 (selectable)	20, 40, 100, 150 (selectable)	Similar
Common Mode Rejection	>118dB (110dB with AC filter disabled)	>140 dB (123 dB with AC filter disabled	Similar
Input Impedance	>=2.5M ohms@10Hz,	.10 M Ohms @10 Hz, defibrillator protected	Similar
Patient Leakage	<10uA	<10 uA	Same
Pace detect	2mV@100us	Orthogonal LA, LL and V6; 750 uV @ 50us	Similar
Display Type	LCD (flat panel display)	LCD (flat panel display)	Same
Display resolution	LCD- 1280 x 1024 or 1920 x 1020	LCD – 1280 x 1024	Similar
Display size	19- to 24-inch LCD	17- or 19-inch LCD	Similar
Monitored Leads	3, 6 or 12	3, 6, 12 or 15	Similar
Displayed Leads	Number on screen 3, 6, 12, 6x2	Number on screen 3, 6, 12, 15	Similar
Display format	3 rhythm, 6 rhythm, 6 x 2, 12 rhythm	3 rhythm, 3 rhythm + medians, 3 rhythm + trends, 6 rhythm, 4 x 2.5 + 1 rhythm, 2 X 6	Similar
Display sensitivity/ gain	2.5, 5, 10, 20 mm/mV	2.5, 5, 10, 20 mm/mV	Same
Displayed vital signs (configurable)	Heart rate, Target heart rate, blood pressure, exercise clock, stage clock, protocol, speed, grade, Watts, METS, RPE, DP, STI and SpO2	Heart rate, Target heart rate, blood pressure, exercise clock, stage clock, phase clock, protocol, speed, grade, Watts, METS, RRP and SpO2	Similar
Displayed data	Zoomed ST, event notification, 3-12 lead waveform, lead map, ST Map, trends report, tabular report, summary report, event report, stored ECG strips, interpretation, time-of-day clock, wireless signal, battery status, patient id/name/DOB, watermark warning messages and prompts	ST scan/median complexes, arrhythmias, ventricular ectopic/min counter, 3 to12 lead waveforms, lead check torso and 12 leads, waterfall display, trends, tabular summary, stored ECG strips, interpretation, time-of-day clock, patient name, warning messages and prompts	Simliar

Specification / Feature	ST80i Stress Test System	CASE V6.6 and CS V6.6 Cardiac Testing Systems	Comparison
Printer technology	"Instant" load, thermal dot array	"Instant" load, thermal dot array	Same
Printer leads	1-12 leads (standard, Cabrera, configurable)	3, 6, 12 or 15 leads (standard, NEHB, Cabrera, configurable)	Similar
Printer Speeds	5, 10, 25 and 50mm/s (+/- 2%)	5, 12.5, 25, and 50 mm/sec (± 2%)	Similar
Printer sensitivity/gain	2.5, 5, 10 or 20mm/mV(+/- 5%)	2.5, 5, 10 or 20 mm/mV (± 5%)	Same
Paper type/size	Thermal, perforated, Z-folded in A size or A4 size	Thermal, perforated, fan folded in A size or A4 size	Similar
Interfaces included	Advanced interface module and Patient interface module; Keyboard/Mouse: USB or wireless; Treadmill or ergometer: USB/RS232; NiBP/SpO2:USB/RS232; 2 analog and 1 TTL output interface; RJ-45 Ethernet; CD drive;	Acquisition module; keyboard (PS/2); dedicated stress keypad (USB); Mouse (PS/2); 100 Mbps Ethernet; 6 serial ports: (COM 1-2, COM A-D), treadmill, BP, ergometer, SpO2; 4 analog and 1 TTL (trigger) output analog ergometer, camera sync, etc.; Diskette drive; CD-R/W drive	Similar
Communication/ Storage types	Network, Local Storage, PDF export of final reports, removable media such USB sticks	Network, Local Storage, PDF export of final reports, XML export of specified data	Similar
Operating System	Windows 7	Windows 2000 Server Windows 2003 Server	Similar
Power Supply	AC operation only	AC operation only	Same
Operating Voltage Range	120± 10% VAC 50-60 Hz; 240± 10% VAC 50-60 Hz	110-120 VAC 50-60 Hz; 200-240 VAC 50-60 Hz	Similar
Biocompatibility	Patient leads, electrodes	Patient leads, electrodes	Same
Sterility	Not applicable	Not applicable	Same

ST80i Stress Test System overall has the same or similar basic technological characteristics to CASE V6.6 and CS V6.6 Cardiac Testing Systems as shown in the table above.

Performance Data

The performance data demonstrated that the ST80i Stress Test System meets the design specifications of the system. The Philips CAlg-STR Exercise ECG Analysis Algorithm which has been incorporated into the ST80i Stress Test System has been previously approved for market under K112959. The Philips ECG Algorithm which has been incorporated into the ST80i Stress Test System has been previously approved for market under K073376.

Conclusions

In conclusion, the performance and non-clinical testing demonstrates that ST80i Stress Test System is as safe and effective as the predicate device. The performance is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 18 2012

Philips Healthcare
c/o Ms. Gretel Lumley
Quality and Regulatory Engineer
1525 Rancho Conejo Boulevard, Suite 100
Thousand Oaks, CA 91320

Re: K121638
Trade/Device Name: ST80i Stress Test System
Regulatory Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: II (two)
Product Code: 74 DQK
Dated: May 31, 2012
Received: June 4, 2012

Dear Ms. Lumley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Appendix A

Indications for Use Statement

510(k) Number: K121638
Device Name: **ST80i Stress Test System**

Indications for Use:

Intended Use

The Philips ST80i Stress Test System is a PC-based diagnostic tool intended to acquire, process, and store ECG data of patients undergoing stress exercise testing. The software records ECG, heart rate, and ST data, creates summary tables, trends, and produces a final report regarding a variety of cardiac data indices. The cardiac data provided by the Stress system is intended to be reviewed, confirmed, and used by trained medical personnel to assist in the evaluation of the patient's cardiovascular condition and the patient's physiological condition during stress exercise testing. The arrhythmia detection portion of the ST80i Stress Exercise System is provided to the user for the convenience of automatic detection of arrhythmias but does not provide alarms.

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Prescription Use (21 CFR 801 Subpart D)	X	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)	

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K121638